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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,187	11/13/2000	Yukiko Sasaki	275352	2634

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/09/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/700,187

Applicant(s)

SASAKI ET AL.

Examiner

Georgia Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

**Invention Disclosure Statement**

1. The Office acknowledges receipt of Applicant's Information Disclosure Statement (PTO-1449), filed 13 November 2000. A signed copy of Applicant's Information Disclosure Statement is enclosed.

***Status of the Claims***

2. Claims 1-13 are pending.

***Claim Rejections - 35 USC § 101***

3. The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 11-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The DNA fragment, promoter, expression cassette, and plant cell are not isolated, and thus read on products of nature.

***Claim Rejections - 35 USC § 112-second***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1,

- The term a "gene" can have several different meanings:
  - A "gene" can mean a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression;
  - Or it can mean a "chimeric" gene which means a heterologous coding sequence functionally linked to a promoter and a terminator which are capable of expressing the coding sequence;
  - Or it can mean a DNA coding sequence.

The Office interprets "gene" to mean "a DNA coding sequence".

- "is repressed" lacks comparative basis. Some state of baseline activity needs to be specified, for "repressed" to have a clear meaning.
- "the presence of light" is unclear because it lacks disclosure of how much light, how long an exposure, and what kind of light. Does "presence of light" encompass everything except complete darkness?
- All subsequent recitations of the above language are also rejected.

Claim 2 does not further limit Claim 1.

In claim 7, drawn to a DNA fragment

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- Since both the “gene” and the “constitutive expression promoter sequence” are downstream of the DNA of SEQ ID NO: 1, it is unclear where the recited constitutive expression promoter sequence is positioned, relative to the gene of claim 1. Which comes first?
- This rejection is made also for SEQ ID 2, of claim 2, and SEQ ID NO: 3, of claim 3.

In claim 8, drawn to a promoter of Claims 4, 5 and 6,

- Since both the “gene” and the “constitutive expression promoter sequence” are downstream of the DNA of the various SEQ ID NO:s, it is unclear where the recited “constitutive expression promoter sequence” is positioned relative to the “gene” of claim 1. Which comes first?

Claim 11 is an improper multiple dependent claim.

Claim 11 recites “a DNA fragment carrying a gene”:

- Which DNA fragment is being referred to? That of claim 1, or that of claim 11?
- “Comprising” or “containing” should be used in place of “carrying”,
- Is “a gene” an additional gene? Or is it the gene of Claim 1?
- In “downstream of the DNA”, which DNA fragment is being referred to?
- “Promoter” lacks antecedent basis.
- “said gene” lacks antecedent basis. Which gene does this refer to? That of claim 11, line 2, or claim 1, line 1?

In claim 12, what is the claimed invention? A plant cell? Or a DNA fragment?

In claim 13,

- “the DNA fragment” is unclear: Which DNA fragment is being referred to?
- “a progeny thereof” is unclear: Which progeny? The plant, or the DNA?
- “a part” is unclear: This can mean a leaf or a cell or a water molecule.

The claims are generally narrative and indefinite, failing to conform to current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Clarification and/or correction is required.

***Claim Rejections - 35 USC § 112-1<sup>st</sup>, enablement***

6. Claims 1, 2, 4, 5, and 7-13, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1 or SEQ ID NO: 2, operatively linked to a constitutive promoter, does not reasonably provide enablement for these SEQ ID Nos without a constitutive promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

SEQ ID NO: 3 is demonstrated to have promoter function.

7. The enablement issues are gene *repression* and *expression*, and a *promoter*:

With respect to *repression* and *expression*,

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a) Applicant claims (claim 1) a DNA fragment where expression ...is repressed. In order for Repression to occur, initially there has to have been expression. Otherwise the term "repression" is meaningless. However, Applicant does not teach expression. Claim 1 is drawn to a DNA fragment comprising the SEQ ID NO: 1, whereby expression is a gene (=coding sequence) placed downstream of the fragment is repressed in the presence of light. However, Applicant provides no evidence that the combination of SEQ ID NO: 1 plus the coding sequence, in and of itself, is expressed. SEQ ID NO: 1 and SEQ ID NO: 2 appear to be enhancer elements and do not have promoter activity. Applicant's specification shows no evidence for expression of such a construct. The state of the art is such that expression of a gene requires a promoter sequence. It would be unpredictable that any DNA fragment would function as a promoter, rather most sequences would not work.

- A DNA sequence search of SEQ ID NO: 1 produced 45 hits out of the first 45 results, all with 100% match. Most of these matched sequences are mammalian DNA sequences, and show no expression or repression function. Therefore, it is highly unpredictable that any DNA fragment containing SEQ ID NO: 1 would function to repress expression.

b) Similarly, the DNA of SEQ ID NO: 2 demonstrates expression only upon insertion of a promoter (CaMV35S) between SEQ ID NO: 2 and the coding sequence.

This has the same problems as for SEQ ID NO: 1, discussed supra.

With respect to a promoter,

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Applicant claims a promoter containing either SEQ ID NO: 1 or SEQ ID NO: 2, where expression of a gene placed downstream of the promoter is promoted in the dark but repressed in the light. Applicant teaches a CaMV 35S promoter and the promoter comprising SEQ ID NO: 3. as having the desired function. Applicant gives no guidance, other than these examples, for selecting a promoter, which would function in the claimed manner. It is unpredictable that any promoter would function in the desired manner. Furthermore, since most promoters are not plant-related promoters, most promoters would **not** work in the claimed invention.

Furthermore, Claims 2 and 5 are drawn to a "nucleotide sequence obtained by deletion, substitution and/ or addition of one or more bases in SEQ ID NO: 2, other than SEQ ID NO: 1". Additions, substitutions and/or deletions encompass many changes, from single nucleotides to very large sequences. No guidance is given other than that the core sequence of SEQ ID NO: 1 be retained in the final sequence. It is unpredictable that any single one of these polynucleotide sequences would function in the same way as SEQ ID NO: 2, in fact most would be nonfunctional. Without further guidance, one of skill in the art would be required to do many experiments involving a myriad of combinations. This would impose a burden on the skilled artisan, without a reasonable expectation of success.

Additionally, a deletion of SEQ ID NO: 2 could produce a DNA fragment containing only SEQ ID NO: 1, which has the *repression* and *expression* issues as discussed above.



In view of the breadth of the claims (any gene, any DNA fragment, any plant and any promoter) and the lack of guidance in the specification, undue experimentation would be required to enable the invention as commensurate in scope with the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Schroeder, et al (Plant Physiology 101: 751-757, 1993). Since SEQ ID NO: 1, SEQ ID NO: 2 and SEQ ID NO: 3 are *Pisum sativum* plant genomic sequences, the claims encompass any transgenic *Pisum sativum* containing a CaMV 35S promoter.

Schroeder teaches

- a *Pisum sativum* plant (p 751, Abstract),
- transformed with

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- an expression cassette comprising a CaMV 35S promoter (p 751, Abstract), operably linked to the neomycin phosphotransferase coding sequence,
- where the 35S/nptII is downstream of SEQ ID NO: 3, which is a pea genomic sequence.

Accordingly, Schroeder anticipates the claimed invention.

10. Claims 1-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Inaba, T et al (Plant Physiol 120, 491-500 (1999) June). Inaba discloses SEQ ID NO: 3 (p 494). Since a certified translation of the Japanese priority document (3/12/99) has not been submitted, the Applicant has benefit of the March 3, 2000 date.

Accordingly, Inaba anticipates the claimed invention.

### **REMARKS**

11. No claims are allowed.

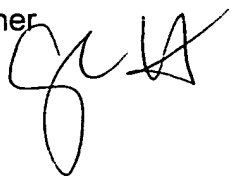
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
May 6, 2002



Phuong Bui  
PHUONG T. BUI  
PRIMARY EXAMINER 5/6/02